Attachment D
510(k) SUMMARY

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CONTACT
Karen Harrington, PhD
Manager, Clinical Affairs
Gen-Probe Prodesse, Inc.
20925 Crossroads Circle
Waukesha, WI 53186

NAME OF DEVICE

Trade Name:	ProGastro SSCS Assay
Regulation Number:	21 CFR 866.3990
Product Code:	PCH and PCI

PREDICATE DEVICE

K121454 Luminex GPP Test

INTENDED USE

The Prodesse® ProGastro SSCS Assay is a multiplex real time PCR *in vitro* diagnostic test for the qualitative detection and differentiation of *Salmonella, Shigella*, and *Campylobacter* (*C. jejuni* and *C. coli* only, undifferentiated) nucleic acids and Shiga Toxin 1 (*stx1*) and Shiga Toxin 2 (*stx2*) genes. Shiga toxin producing *E. coli* (STEC) typically harbor one or both genes that encode for Shiga Toxins 1 and 2. Nucleic acids are isolated and purified from preserved stool specimens obtained from symptomatic patients exhibiting signs and symptoms of gastroenteritis. This test is intended for use, in conjunction with clinical presentation and epidemiological risk factors, as an aid in the differential diagnosis of *Salmonella, Shigella, Campylobacter jejuni/Campylobacter coli*, and STEC infections in humans.

The results of this test should not be used as the sole basis for diagnosis, treatment, or other patient management decisions. Positive results do not rule out co-infection with other organisms that are not detected by this test, and may not be the sole or definitive cause of patient illness. Negative ProGastro SSCS Assay results in the setting of clinical illness compatible with gastroenteritis may be due to infection by pathogens that are not detected by this test or non-infectious causes such as ulcerative colitis, irritable bowel syndrome, or Crohn's disease.

PRODUCT DESCRIPTION

The ProGastro SSCS Assay enables detection and differentiation of *Salmonella, Shigella, Campylobacter* (*C. jejuni* and *C. coli* only, undifferentiated) and an Internal Control in the SSC Mix and Shiga Toxin Producing *E. coli* (STEC, *stx1* and *stx2* differentiated) and an Internal Control in the STEC Mix.

An overview of the procedure is as follows:

1. Collect raw stool specimens from symptomatic patients and place into Cary Blair Transport Medium or ParaPak C&S (C&S) Transport Medium .
2. Add the Gastro RNA/DNA Internal Control (GIC) to every sample to monitor for inhibitors present in the specimens.
3. Perform isolation and purification of nucleic acids using a NucliSENS easyMAG System and the

Automated Magnetic Extraction Reagents (bioMérieux).

4. Add purified nucleic acids to the **SSC Mix** included in the ProGastro SSCS Assay Kit. The SSC Mix contains target-specific oligonucleotide primers and probes for detection of *Salmonella*, *Shigella*, and *Campylobacter* (*C. jejuni* and *C. coli* only). The primers and probes are complementary to highly conserved regions of genetic sequences for these organisms. The probes are dual-labeled with a reporter dye and a quencher (see table below).
5. Add purified nucleic acids to the **STEC Mix** included in the ProGastro SSCS Assay Kit. The STEC Mix contains target-specific oligonucleotide primers and probes for detection of Shiga Toxin 1 and 2 genes (*stx1* and *stx2*). The primers and probes are complementary to highly conserved regions of these genes. The probes are dual-labeled with a reporter dye and a quencher (see table below).
6. Perform amplification of DNA in a Cepheid SmartCycler II instrument. In this process, the probe anneals specifically to the template followed by primer extension and amplification. The ProGastro SSCS Assay is based on Taqman reagent chemistry, which utilizes the 5' – 3' exonuclease activity of Taq polymerase to cleave the probe thus separating the reporter dye from the quencher. This generates an increase in fluorescent signal upon excitation from a light source. With each cycle, additional reporter dye molecules are cleaved from their respective probes, further increasing fluorescent signal. The amount of fluorescence at any given cycle is dependent on the amount of amplification products present at that time. Fluorescent intensity is monitored during each PCR cycle by the real-time instrument.

Supermix	Analyte	Gene Targeted		Probe Fluorophore	Absorbance Peak	Emission Peak	Instrument Channel
SSC Mix	*Campylobacter* (*C. jejuni* and *C. coli* only)	*C. jejuni* *glyA*	*C. coli* *cadF*	FAM	495 nm	520 nm	FAM
SSC Mix	*Salmonella spp.*	*orgC*		CAL Fluor Orange 560	538 nm	559 nm	TET
SSC Mix	*Shigella spp.*	*ipaH*		CAL Fluor Red 610	590 nm	610 nm	Texas Red
STEC Mix	Shiga Toxin 1	*stx1*		CAL Fluor Orange 560	538 nm	559 nm	TET
STEC Mix	Shiga Toxin 2	*stx2*		FAM	495 nm	520 nm	FAM
SSC Mix and STEC Mix	Internal Control	NA		Quasar 670	647 nm	670 nm	Cy5

SUBSTANTIAL EQUIVALENCE

Similarities		
Element	**Prodesse ProGastro SSCS (k123274)**	**Luminex xTAG GPP (k121454)**
Organisms Detected	*Salmonella spp.*, *Shigella spp.*, *Campylobacter* (*C. jejuni* and *C. coli*), and STEC (*stx1* and *stx2* genes)	Same (See below for differences)
Analyte	DNA	(See below for differences)
Technological Principles	Multiplex nucleic acid	Same (See below for differences)
Specimen Types	Stool specimens	Same
User Complexity	High	Same
Sample Preparation Method	Up front sample processing is required to extract nucleic acids	Same
Controls	Internal control in each sample. External control processed with each batch of samples.	Same
Differences		
Element	**Prodesse ProGastro SSCS (k123274)**	**Luminex xTAG GPP (k121454)**
Organisms Detected	(See above for similarities)	Can also detect and distinguish *C. lari*. In addition, can detect and distinguish *Clostridium difficile toxin A/B, Cryptosporidium (C. parvum and C. hominis only), Escherichia coli (E. coli) O157,* Enterotoxigenic *E. coli* (ETEC) LT/ST, *Giardia (G. lamblia only),* Norovirus GI/GII, and Rotavirus A.
Analyte	DNA	RNA/DNA
Technological Principles	Real time multiplex PCR based on the Taqman reagent chemistry	Multiplex RT-PCR and bead hybridization followed by Fluorescence-activated sorting of labeled beads coupled to streptavidin-conjugated biotinylated products
Instrumentation	Cepheid SmartCycler II	PCR Thermocycler and Luminex 100/200 system
Time to result	Approximately 3 hours	Approximately 6 to 12 hours

Clinical Performance

Prospective Study

The clinical performance of the ProGastro SSCS Assay was established during prospective studies at four U.S. clinical laboratories. Leftover stool samples were collected during July 2011 – November 2011 and May 2012 – July 2012 and tested during November 2011 thru August 2012. All specimens used in the study meeting the inclusion criteria represented excess remnants of stool specimens that were prospectively collected from symptomatic individuals suspected of gastrointestinal infection, and were submitted for routine care or analysis by each site, and that otherwise would have been discarded.

Demographic details for the patient population included in the prospective study are summarized in the following table.

Sex	Number of Samples SSC Mix	Number of Samples STEC Mix
Male	615/1214 (50.6%)	615/1214 (50.6%)
Female	581/1214 (47.9%)	581/1214 (47.9%)
Unknown	18/1214 (1.5%)	18/1214 (1.5%)
Age (yrs)		
≤ 5 years	378/1214 (31.1%)	378/1214 (31.1%)
6 - 18 years	296/1214 (24.4%)	296/1214 (24.4%)
19 – 64 years	357/1214 (29.4%)	357/1214 (29.4%)
≥ 65 years	164/1214 (13.5%)	164/1214 (13.5%)
Unknown	19/1214 (1.6%)	19/1214 (1.6%)

Performance of the ProGastro SSCS Assay was assessed and compared to the reference method of culture (*Campylobacter*, *Salmonella*, and *Shigella*) or broth enrichment followed by FDA cleared EIA test (Shiga Toxin producing *E. coli*). Samples positive for STEC by broth/EIA and/or the ProGastro SSCS Assay underwent PCR followed by bi-directional sequencing to confirm the presence of the *stx1* and/or *stx2* genes. Two PCR/sequencing assays were used that each targeted different regions of the *stx1* or *stx2* gene than the ProGastro SSCS Assay. "True" STEC positives were considered as any sample that tested positive for STEC by the broth/EIA method, and "True" STEC negatives were considered as any sample that tested negative for STEC by the broth/EIA method. "True" *stx1* or "true" *stx2* positives were considered as any sample that tested positive for STEC by the broth/EIA method and by PCR/sequencing. Bi-directional sequencing data was required to meet pre-defined quality acceptance criteria for both the forward and the reverse sequences that matched *stx1* or *stx2* sequences deposited in the National Center for Biotechnology Information (NCBI) GenBank database (www.ncbi.nlm.nih.gov), respectively, with acceptable E-values. The E-Value from NCBI BLAST Alignment indicates the statistical significance of a given pair-wise alignment and reflects the size of the database and the scoring system used. The lower the E-Value, the more significant the hit is. A sequence alignment that has an E-Value of 1e-3 means that this similarity has a 1 in 1000 chance of occurring by chance alone. (http://www.ncbi.nlm.nih.gov/books/bv.fcgi?rid=handbook.section.614).

Discrepant results between the ProGastro SSCS Assay and the reference methods were also evaluated using analytically validated PCR/sequencing assays and results are footnoted in the performance tables below.

A total of 1214 patients were initially enrolled in the prospective clinical trial. Prospective stool specimens were initially included in the prospective clinical trial. Sixty-one (61) patient/specimens were excluded from the performance calculations due to deviations from the clinical study protocol. Fourteen (14) specimens were excluded for the SSC Mix and 14 were excluded for the STEC Mix from the prospective clinical study data analysis because they remained "Unresolved" after repeat testing with the respective ProGastro SSCS Assay Mix. Unresolved results occur when the sample is negative for all target detections and the Internal Control, indicating potentially PCR-inhibited samples. This resulted in a total of 1139 eligible prospective specimens to be included in the prospective clinical study data analysis.

Campylobacter (C. jejuni / C. coli) Comparison Results

		Culture			
		Positive	**Negative**	**Total**	
ProGastro SSCS Assay	**Positive**	20	13[a]	**33**	**Sensitivity 100.0%** (83.9% - 100.0%) 95% CI
	Negative	0	1106	**1106**	**Specificity 98.8%** (98.0% - 99.3%) 95% CI
	Total	**20**	**1119**	**1139**	

[a] Six (6) samples were positive for *Campylobacter* (*C. coli* or *C. jejuni*) by bi-directional sequence analysis.

Salmonella Comparison Results

		Culture			
		Positive	**Negative**	**Total**	
ProGastro SSCS Assay	**Positive**	20	10[a]	**30**	**Sensitivity 95.2%** (77.3% - 99.2%) 95% CI
	Negative	1[b]	1108	**1109**	**Specificity 99.1%** (98.4% - 99.5%) 95% CI
	Total	**21**	**1118**	**1139**	

[a] Ten (10) samples were positive for *Salmonella* by bi-directional sequence analysis.
[b] Sample was positive for *Salmonella* by bi-directional sequence analysis.

Shigella Comparison Results

		Culture			
		Positive	**Negative**	**Total**	
ProGastro SSCS Assay	**Positive**	15	6[a]	**21**	**Sensitivity 100.0%** (79.6% - 100.0%) 95% CI
	Negative	0	1118	**1118**	**Specificity 99.5%** (98.8% - 99.8%) 95% CI
	Total	**15**	**1124**	**1139**	

[a] Six (6) samples were positive for *Shigella* by bi-directional sequence analysis.

STEC Comparison Results

		Broth Enrichment/EIA			
		Positive	**Negative**	**Total**	
ProGastro SSCS Assay	**Positive**	9[a]	9[b]	**18**	**Sensitivity** 100.0% (70.1% - 100.0%) 95% CI
	Negative	0	1121	**1121**	**Specificity** 99.2% (98.5% - 99.6%) 95% CI
	Total	**9**	**1130**	**1139**	

[a] Six (6) samples positive for *stx1*, one (1) sample positive for *stx2*, and two (2) samples positive for *stx1* and *stx2* by bi-directional sequence analysis.
[b] Six (6) samples positive for *stx1* and three (3) samples positive for *stx2* by bi-directional sequence analysis.

stx1 Comparison Results

		Broth Enrichment/EIA and sequencing for stx1			
		Positive	**Negative**	**Total**	
ProGastro SSCS Assay	**Positive**	8	6[a]	**14**	**Positive Percent Agreement 100.0%** (67.6% - 100.0%) 95% CI
	Negative	0	4	**4**	**Negative Percent Agreement 40.0%** (16.8% - 68.7%) 95% CI
	Total	**8**	**10**	**18**	

[a] Six (6) samples negative by broth/EIA, five (5) were positive for *stx1* by bi-directional sequencing, but were negative by Broth Enrichment/EIA.

stx2 Comparison Results

		Broth Enrichment/EIA and sequencing for stx2			
		Positive	**Negative**	**Total**	
ProGastro SSCS Assay	**Positive**	3	3[a]	**6**	**Positive Percent Agreement 100.0%** (43.9% - 100.0%) 95% CI
	Negative	0	12	**12**	**Negative Percent Agreement 80.0%** (54.8% - 93.0%) 95% CI
	Total	**3**	**15**	**18**	

[a] Three (3) samples were positive for *stx2* by bi-directional sequence analysis, but were negative by Broth Enrichment/EIA.

The ProGastro SSCS Assay detected one mixed infections in the prospective clinical evaluation. This represents 0.98% of the total positive specimens (1/102). The one mixed infections sample was double infections and was confirmed by the reference methods.

Distinct Co-infection Combinations Detected by the ProGastro SSCS Assay in the Prospective Clinical Trial

Distinct Co-infection Combinations Detected by ProGastro SSCS Assay			Total Co-infections	Number of Discrepant Co-infections[a]	Discrepant Analyte(s)[a]
Analyte 1	Analyte 2	Analyte 3			
Salmonella	*Campylobacter*	N/A	0	0	
Salmonella	*Shigella*	N/A	0	0	
Salmonella	STEC	N/A	0	0	
Campylobacter	*Shigella*	N/A	0	0	
Campylobacter	STEC	N/A	1	0	
STEC	*Shigella*	N/A	0	0	
Salmonella	*Campylobacter*	STEC	0	0	
Total Co-infections			1	0	
Total Double Infections			1	0	
Total Triple Infections			0	0	

[a]A discrepant co-infection or discrepant analyte was defined as one that was detected by the ProGastro SSCS Assay but not detected by the reference methods.

There were no co-infections that were detected by the reference method and not detected by the ProGastro SSCS Assay.

Retrospective Study

In addition to the prospective clinical study, two clinical sites also performed testing using retrospective samples that were collected from 2007 - 2011. A total of 105 stool samples were included in the retrospective study. These samples had been previously determined to be positive or negative by culture and/or Broth Enrichment/EIA. The ProGastro SSCS Assay was compared to the same reference method that was employed for the prospective study to determine positive and negative percent agreement.

Demographic details for this patient population are summarized in the table below.

Sex*	Number of Subjects
Female	24/55 (43.6%)
Male	31/55 (56.4%)
Age	**Number of Subjects**
≤ 5 years	12/105 (11.4%)
6 - 18 years	24/105 (22.9%)
19 – 64 years	51/105 (48.6%)
≥ 65 years	18/105 (17.1%)

*For all of the 50 specimens tested from one site the gender was unknown

Campylobacter Comparison Results

		Culture			
		Positive	**Negative**	**Total**	
ProGastro SSCS Assay	**Positive**	27	5	**32**	**Positive Percent Agreement 96.4%** (82.3% - 99.4%) 95% CI
	Negative	1	72	**73**	**Negative Percent Agreement 93.5%** (85.7% - 97.2%) 95% CI
	Total	**28**	**77**	**105**	

Salmonella Comparison Results

		Culture			
		Positive	**Negative**	**Total**	
ProGastro SSCS Assay	**Positive**	3	0	**3**	**Positive Percent Agreement 100.0%** (43.4% - 100.0%) 95% CI
	Negative	0	102	**102**	**Negative Percent Agreement 100.0%** (96.4% - 100.0%) 95% CI
	Total	**3**	**102**	**105**	

Shigella Comparison Results

		Culture			
		Positive	**Negative**	**Total**	
ProGastro SSCS Assay	**Positive**	4	0	**4**	**Positive Percent Agreement 100.0%** (51.0% - 100.0%) 95% CI
	Negative	0	101	**101**	**Negative Percent Agreement 100.0%** (96.3% - 100.0%) 95% CI
	Total	**4**	**101**	**105**	

STEC Comparison Results

		Culture or Broth Enrichment/EIA			
		Positive	**Negative**	**Total**	
ProGastro SSCS Assay	**Positive**	19[a]	0	**19**	Positive Percent Agreement 100.0% (83.2% - 100.0%) 95% CI
	Negative	0	86	**86**	Negative Percent Agreement 100.0% (95.7% - 100.0%) 95% CI
	Total	**19**	**86**	**105**	

[a] Five (5) samples positive for *stx1*, 5 samples positive for *stx2*, and 9 samples positive for *stx1* and *stx2*.

stx1 Comparison Results

		Culture or Broth Enrichment/EIA and sequencing for stx1			
		Positive	**Negative**	**Total**	
ProGastro SSCS Assay	**Positive**	14	0	**14**	Positive Percent Agreement 100.0% (78.5% - 100.0%) 95% CI
	Negative	0	5	**5**	Negative Percent Agreement 100.0% (56.6% - 100.0%) 95% CI
	Total	**14**	**5**	**19**	

stx2 Comparison Results

		Culture or Broth Enrichment/EIA and sequencing for stx2			
		Positive	**Negative**	**Total**	
ProGastro SSCS Assay	**Positive**	14	0	**14**	Positive Percent Agreement 100.0% (78.5% - 100.0%) 95% CI
	Negative	0	5	**5**	Negative Percent Agreement 100.0% (56.6% - 100.0%) 95% CI
	Total	**14**	**5**	**19**	

Of the prospective and retrospective specimens run using the SSC Mix Assay, 98.0% (1233/1258) of these specimens were successful on the first attempt. The remaining 25 (25/1258 = 2.0%) gave "Unresolved" results on the first attempt. An "Unresolved" result is generated when the Gastro Internal Control (GIC) fails to be detected in a clinical specimen. A failure of the GIC to be detected can occur if inhibitors are present in a sample or due to technical error (e.g., GIC not added prior to nucleic acid extraction). Of the 25 "Unresolved" specimens on the first attempt with sufficient nucleic acid for retest, 44.0% (11/25) gave a valid result on the second attempt. The remaining 14 were "Unresolved" on the second attempt.

Of the prospective and retrospective specimens run using the STEC Mix Assay, 97.9% (1232/1258) of these specimens were successful on the first attempt. The remaining 26 (26/1258 = 2.1%) gave "Unresolved" results on the first attempt. Of the 26 "Unresolved" specimens on the first attempt with sufficient nucleic acid for retest, 48.0% (12/25) gave a valid result on the second attempt. The remaining 14 were "Unresolved" on the second attempt.

Reproducibility

The reproducibility of the ProGastro SSCS Assay was evaluated at three laboratory sites. Reproducibility was assessed using a panel of 15 simulated samples that included medium positive, low positive (near the assay limit of
detection, ≥ 95% positive), and high negative (below the assay limit of detection, ≤ 95% positive) samples for each of the assay targets. The reproducibility panel and controls were run with the ProGastro SSCS Assay (SSC and STEC Mixes) at three sites by each of two operators per site for five days.

Reproducibility Panel Member Results

		SSC Mix								STEC Mix				SSC Mix	STEC Mix
	Panel Member ID	***C. jejuni* Low Positive**	***C. jejuni* Medium Positive**	***C. coli* Low Positive**	***C. coli* Medium Positive**	***Salmonella* Low Positive**	***Salmonella* Medium Positive**	***Shigella* Low Positive**	***Shigella* Medium Positive**	**STEC (*stx 1*) Low Positive**	**STEC (*stx 1*) Medium Positive**	**STEC (*stx 2*) Low Positive**	**STEC (*stx 2*) Medium Positive**	**High Negative (IC Ct Value)**	**High Negative (IC Ct Value)**
	Concentration	20X* LoD	100X* LoD	6X* LoD	30X* LoD	2X LoD	10X LoD	2X LoD	10X LoD	2X LoD	10X LoD	2X LoD	10X LoD	0.0001X LoD	
Site 1	Agreement with Expected Result	30/30 100%	30/30 100%	30/30 100%	30/30 100%	30/30 100%	30/30 100%	30/30 100%	30/30 100%	30/30 100%	30/30 100%	30/30 100%	30/30 100%	90/90 100%	90/90 100%
	Mean Ct Value	37.6	35.2	35.9	33.5	35.9	33.2	35.8	33.2	36.1	33. 4	36.7	34. 5	33.6	33.2
	% CV	3.5	3.0	3.9	3.7	1.4	1.2	1.7	1.4	2.0	1.6	1.8	1.3	3.0	1.7
Site 2	Agreement with Expected Result	30/30 100%	30/30 100%	30/30 100%	30/30 100%	30/30 100%	30/30 100%	29/30 96.7%	30/30 100%	30/30 100%	30/30 100%	30/30 100%	30/30 100%	90/90 100%	90/90 100%
	Mean Ct Value	37.3	34.8	35.8	33.4	36.0	33.1	35.6	33.2	36.2	33.6	36.8	34.7	33.3	33.0
	% CV	3.0	2.8	3.1	3.2	1.7	1.6	1.9	1.8	2.5	1.6	1.9	1.9	0.9	0.9
Site 3	Agreement with Expected Result	30/30 100%	30/30 100%	30/30 100%	30/30 100%	30/30 100%	30/30 100%	30/30 100%	30/30 100%	30/30 100%	30/30 100%	30/30 100%	30/30 100%	90/90 100%	90/90 100%
	Mean Ct Value	37.0	34.4	35.2	32.9	35.7	32.7	35.0	32.8	35.6	33.1	36.5	34.2	32.9	32.6
	% CV	2.6	2.2	2.1	1.9	1.4	1.2	1.8	1.3	1.7	1.3	1.6	1.0	0.8	1.1
	Total Agreement with Expected Result	90/90 100%	90/90 100%	90/90 100%	90/90 100%	90/90 100%	90/90 100%	89/90 89.9%	90/90 100%	90/90 100%	90/90 100%	90/90 100%	90/90 100%	270/270 100%	270/270 100%
	95% CI	95.9%-100.0%	95.9%-100.0%	95.9%-100.0%	95.9%-100.0%	95.9%-100.0%	95.9%-100.0%	94.0%-99.8%	95.9%-100.0%	95.9%-100.0%	95.9%-100.0%	95.9%-100.0%	95.9%-100.0%	98.6%-100.0%	98.6%-100.0%
	Overall Mean Ct Value	37.3	34.8	35.6	33.3	35.9	33.0	35.5	33.1	35.9	33.4	36.7	34.5	33.2	32.9
	Overall % CV	3.1	2.8	3.2	3.1	1.6	1.5	2.0	1.6	2.2	1.6	1.8	1.5	2.1	1.5

* Note: The *Campylobacter* strains were tested at higher concentrations because *Campylobacter* is sensitive to environmental stressors including freezing where it loses viability. However, the average Ct value for the *C. jejuni* (ATCC 33291) Low Positives was 37.3, which is very close to the average Ct value of 38.8 for the same *C. jejuni* strain tested at the estimated LoD level in the Analytical Reactivity Study. The average Ct value for the *C. coli* (ATCC BAA-371) Low Positives was 35.6, which is very close to the average Ct value of 34.4 for the same *C. coli* strain tested at the estimated LoD level in the Analytical Reactivity Study. Therefore, the effective DNA concentrations of the *C. jejuni* (ATCC 33291) and *C. coli* (ATCC BAA-371) low positive samples tested in the Reproducibility Study are very close to the estimated LoD DNA concentrations for these two strains tested in the Analytical Reactivity Study.

Precision

The precision of the ProGastro SSCS Assay was evaluated internally using a panel of 15 simulated samples that included medium positive, low positive (near the assay limit of detection, ≥ 95% positive), and high negative (below the assay limit of detection, ≤ 95% positive) samples for each of the assay targets. A panel of 15 contrived samples including the necessary controls was run with the ProGastro SSCS Assay (SSC and STEC Mixes) by each of two operators for twelve days.

Precision Panel Member Results

	SSC Mix								STEC Mix				SSC Mix	STEC Mix
Panel Member ID	***C. jejuni* Low Positive**	***C. jejuni* Medium Positive**	***C. coli* Low Positive**	***C. coli* Medium Positive**	***Salmonella* Low Positive**	***Salmonella* Medium Positive**	***Shigella* Low Positive**	***Shigella* Medium Positive**	**STEC (*stx 1*) Low Positive**	**STEC (*stx 1*) Medium Positive**	**STEC (*stx 2*) Low Positive**	**STEC (*stx 2*) Medium Positive**	**High Negative (IC Ct Value)**	**High Negative (IC Ct Value)**
Concentration	20X* LoD	100X* LoD	6X* LoD	30X* LoD	2X LoD	10X LoD	2X LoD	10X LoD	2X LoD	10X LoD	2X LoD	10X LoD	0.0001X LoD	
Total Agreement with Expected Result	72/72 100%	72/72 100%	72/72 100%	72/72 100%	72/72 100%	72/72 100%	72/72 100%	72/72 100%	72/72 100%	72/72 100%	72/72 100%	72/72 100%	71/72 98.6%	72/72 100%
Overall Mean Ct Value	36.7	34.2	35.0	32.7	35.6	32.7	35.1	32.7	35.6	33.0	36.5	34.2	32.9	32.5
Overall % CV	2.6	2.4	2.1	2.3	1.5	1.1	1.6	1.3	1.8	1.3	1.8	1.2	0.9	1.0

* Note: The *Campylobacter* strains were tested at higher concentrations because *Campylobacter* is sensitive to environmental stressors including freezing where it loses viability. However, the average Ct value for the *C. jejuni* (ATCC 33291) Low Positives was 37.3, which is very close to the average Ct value of 38.8 for the same *C. jejuni* strain tested at the estimated LoD level in the Analytical Reactivity Study. The average Ct value for the *C. coli* (ATCC BAA-371) Low Positives was 35.6, which is very close to the average Ct value of 34.4 for the same *C. coli* strain tested at the estimated LoD level in the Analytical Reactivity Study. Therefore, the effective DNA concentrations of the *C. jejuni* (ATCC 33291) and *C. coli* (ATCC BAA-371) low positive samples tested in the Precision Study are very close to the estimated LoD DNA concentrations for these two strains tested in the Analytical Reactivity Study.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center – WO66-G609
Silver Spring, MD 20993-002

Gen-Probe Prodesse, Inc.
c/o Karen Harrington, Ph.D.
Manager, Clinical Affairs
20925 Crossroads Circle
Waukesha, WI 53186

JAN 16 2013

Re: k123274
Trade/Device Name: ProGastro SSCS Assay
Regulation Number: 21 CFR 866.3990
Regulation Name: Gastrointestinal Microorganism Multiplex Nucleic Acid-Based Assay
Regulatory Class: Class II
Product Code: PCH, PCI, OOI
Dated: October 17, 2012
Received: October 19, 2012

Dear Dr. Harrington:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set

forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Parts 801 and 809), please contact the Office of *In Vitro* Diagnostics and Radiological Health at (301) 796-5450. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

Uwe Scherf for

Sally A. Hojvat, M.Sc., Ph.D.
Director
Division of Microbiology Devices
Office of *In Vitro* Diagnostics and Radiological Health
Center for Devices and Radiological Health

Enclosure

Indication for Use

510(k) Number: k123274

Device Name: ProGastro SSCS Assay

Indication For Use:

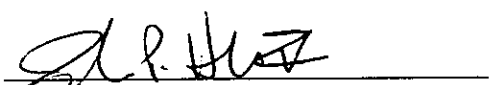
The Prodesse® ProGastro SSCS Assay is a multiplex real time PCR *in vitro* diagnostic test for the qualitative detection and differentiation of *Salmonella*, *Shigella*, and *Campylobacter* (*C. jejuni* and *C. coli* only, undifferentiated) nucleic acids and Shiga Toxin 1 (*stx1*) and Shiga Toxin 2 (*stx2*) genes. Shiga toxin producing *E. coli* (STEC) typically harbor one or both genes that encode for Shiga Toxins 1 and 2. Nucleic acids are isolated and purified from preserved stool specimens obtained from symptomatic patients exhibiting signs and symptoms of gastroenteritis. This test is intended for use, in conjunction with clinical presentation and epidemiological risk factors, as an aid in the differential diagnosis of *Salmonella, Shigella, Campylobacter jejuni/Campylobacter coli*, and STEC infections in humans.

The results of this test should not be used as the sole basis for diagnosis, treatment, or other patient management decisions. Positive results do not rule out co-infection with other organisms that are not detected by this test, and may not be the sole or definitive cause of patient illness. Negative ProGastro SSCS Assay results in the setting of clinical illness compatible with gastroenteritis may be due to infection by pathogens that are not detected by this test or non-infectious causes such as ulcerative colitis, irritable bowel syndrome, or Crohn's disease.

Prescription Use ___X___ (21 CFR Part 801 Subpart D) And/Or Over the Counter Use ____. (21 CFR Part 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE; CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of *In Vitro* Diagnostics and Radiological Health (OIR)



Division Sign-Off
Office of *In Vitro* Diagnostics and Radiological Health
k123274